UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,992	12/14/2001	Bernhard Hanke	08056-1-0020	7145

26135 7590 01/15/2003

LOTT & FRIEDLAND, P.A.
P.O. BOX 141098
CORAL GABLES, FL 33114-1098

EXAMINER
ZIMMER, MARC S

ART UNIT	PAPER NUMBER
1712	4

DATE MAILED: 01/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

mk -4

Office Action Summary	Application No.	Applicant(s)	
	10/017,992	HANKE ET AL.	
	Examiner	Art Unit	
	Marc S. Zimmer	1712	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,2,6 and 7* is/are allowed.

6)☒ Claim(s) *3-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Priority

Applicant claims priority pursuant to 35 U.S.C § 119(a) and 365(b). However, these statutes do not apply to situations in which the U.S. filing is claiming the benefit of priority to a PCT application. To receive the benefit of priority back to the filing date of a PCT (or even earlier if the PCT filing, itself, claims priority to a preceding filing in a foreign office), the Application should be filed either as a national stage application per the provisions of 35 U.S.C § 371 or as a continuation application under 35 U.S.C 120. Section 1895 of the MPEP provides direction on this matter. Applicant should provide proof that the PCT was still copending as of the time that the present application was filed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4, and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a

question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 3 and 4 outline both large and more confining ranges that are to be satisfied for the amount and size respectively of the silver nanoparticles.

As for claim 5, there is insufficient antecedent basis in claim 1 for a *fluid* organic matrix as it does not disclose the physical state of this component of the invention.

Allowable Subject Matter

Applicant discloses a composition comprised of a polysiloxane host material containing a homogeneous dispersion of elemental silver having a particle size of between 1 and 50 nm. The degree of silver incorporation will be sufficiently high to confer upon the composition an antimicrobial property. At the same time, the amount of silver nanoparticle incorporation should not be so high as render the composition poisonous to tissues.

It has long been known that silver metal and its compounds exert an antimicrobial effect upon materials. Crossley, U.S. Patent # 4,054,139 appears to provide one of the earliest reports of this effect wherein he describes a catheter that is coated with a composition featuring small quantities of silver metal. Alternatively, silver may be incorporated directly into the catheter. In either case, the polymer materials from which the coating or catheter is prepared are not disclosed. Laurin et al., U.S.

Patent # 4,677,143 disclose compositions, and articles derived therefrom, comprising polymers such as RTV silicones and metals/metal compounds that exhibit antimicrobial activity. Laurin states that the selection of metals having large- or small particle size will depend on the desired effect. In particular, large particle size is advantageous where a high initial dose and short period of effectiveness are needed. Conversely, small particle size is beneficial when only a low initial dose and extended efficacy are required. However, insofar as *Laurin* does not define what precisely is meant by "large" and "small", it fails to anticipate the instant invention. Pratt et al., U.S. Patent # 4,849,223 teaches that silver is an especially efficient antimicrobial agent when used in concert with titanium- or tantalum oxide. Further, they instruct that the morphological form that the silver takes is not crucial. Like Laurin, Pratt does not expressly teach a preferred particle size hence the invention is allowable over Pratt.

Ogle et al., U.S. Patent # 6,267,782 also teaches a silver-filled biocompatible material that may be used in the manufacture of biomedical articles. In contrast to the aforementioned inventions, Ogle does not contemplate the direct addition of a particulate silver fraction to a silicone. Instead, they contemplate incorporating a soluble silver salt as a precursor to elemental silver after which the salt is reduced by one of several techniques including chemical- (Tollen's reagent) or photolytic reduction. The reference is silent as to the size of the silver domains created by these methods. Therefore, Ogle also fails to anticipate the instant invention.

Other antimicrobial compositions disclosed in the prior art feature silver attached to an inorganic support as is the case in Sakamoto et al., U.S. Patent # 6,121,298 and

Ketayama, JP 2000-95976 A. Sturmann et al., U.S. Patent Application Publication # 2002/0115873, teaches the formation of supported nanometer-sized precious metals wherein the supports are prepared by sol gel processes involving at least one reactant having Si-H bonds. Though the particle size of the precious metal component adheres to the requirements set forth in claim 1, the particles are not homogeneously dispersed in an organic medium but, rather, reside on a solid surface instead. *In arguendo*, this document does not qualify as a reference because the effective filing date does not antedate even the U.S. filing date of the present application.

The references mentioned above are hardly intended to represent a comprehensive review of the subject area. Indeed, they are offered only as examples of the variety of compositions that feature silver as an antimicrobial agent. Nonetheless, they mirror the prior art at large in that none of them disclose a silicone matrix into which has been incorporated a particulate silver material having a particle dimension on the nanometer scale. Accordingly claims 1-7 are allowable over the prior art.

Any inquiry oncerning this communication or earlier communications from the examiner should be directed to Marc S. Zimmer whose telephone number is 703-605-1176. The examiner can normally be reached on Monday-Friday 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Dawson can be reached on 703-308-2340. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

January 8, 2003

Robert Dawson
Supervisory Patent Examiner
Technology Center 1700